510(k) Summary (K083480)

MAY - 5 2009

Submitter: Inclusive Dental Solutions
4141 MacArthur Blvd.
Newport Beach, CA 92660

Contact Person(s): Keith D. Allred, 949-440-2683 (p) / 949-440-2787 (f)
and consultants, Greg Minzenmayer & Grant Bullis

Date of Application: November 14, 2008

Device Name, Type and Classification: Inclusive Zirconia Abutment Blanks, product code "NHA," non-exempt Class II (Sec. 872.3630 - Endosseous dental implant abutment)

Indications for Use:

The Inclusive Zirconia Abutment Blank is intended to be used in conjunction with endosseous implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

Inclusive Zirconia Abutment Blanks for Zimmer Implants are compatible with Zimmer Screw Vent and Tapered Screw Vent internal hex implants. Inclusive Zirconia Abutment Blanks for *3i* Implant are compatible with *3i* Certain internal hex implants. Inclusive Zirconia Abutment Blanks for Nobel Biocare Implant are compatible with Nobel Biocare Replace straight and tapered internal-connection implants.

Abutments with angulations greater than 20 degrees are contraindicated.

Substantial Equivalence: The device is substantially equivalent to other legally marketed devices in the United States. Substantially equivalent devices include the following: Biomet 3i Dental Abutments cleared under K072642; for Zimmer, Biomet3i and Nobel Biocare implants cleared under K011028, K063341, and K023113 respectively; Atlantis™ Abutment in Zirconia for Nobel Biocare Replace (K062277); and, Atlantis™ Abutment in Zirconia for 3i Certain (K072483).

Safety and Efficacy: The device functions in a similar manner to other comparative devices and the intended use is the same. The differences between comparative devices are minor and do not raise new safety concerns. The effectiveness and suitability to the intended purpose of the device is assured through wide, general use of similar other predicate devices, and demonstrates the safe use of the device to construct dental restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Keith D. Allred
Inclusive Dental Solutions
4141 MacArthur Boulevard
Newport Beach, California 92660

Re: K083480
Trade/Device Name: Inclusive Zirconia Abutment Blanks
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 21, 2009
Received: April 22, 2009

Dear Mr. Allred:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Schedule B

Indications for Use Statement

510(k) Number: K083480

Device Name: Inclusive Zirconia Abutment Blanks

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Prescription Use __X__ (Part 21 CFR 801 SubpartD) AND/OR Over-The-Counter Use ____ (21 CFR 801 SubpartC)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kori Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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